(4)

No. 05-1006

In the Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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INTRODUCTION

The Federal Circuit has introduced into Article III a limitation on the subject matter jurisdiction of federal courts in declaratory judgment actions that runs contrary to established precedent of this Court, and that decisions of other circuits have rejected. Further, by its ruling, the court of appeals denied jurisdiction in a class of federal cases in which Congress specifically authorized declaratory judgment actions in order to accelerate the introduction of generic drugs and thereby moderate the explosive growth in expenditures on prescription drugs.

Pfizer's opposition ignores this Court's settled Article III jurisprudence, the decisions of other circuits applying this jurisprudence, and the importance of the questions presented for national health care policy. The petition for a writ of certiorari should be granted.

I. The Issues Presented For Review Will Continue To Affect Consumers And ANDA Applicants For Years, If Not Decades, To Come.

Pfizer states that Apotex's petition "raises no important or recurring issue warranting this Court's review . . . ." (Pfizer Opp'n at 9). This is so, according to Pfizer, "because of amendments to the key provisions of the statute . . . ." (*Id.* at 10). Pfizer is wrong. The issues presented here will continue to severely harm ANDA applicants and the public as long as the *Teva* decision remains in effect.

As an initial matter, Pfizer advanced this "unlikely to recur" argument when opposing Teva's certiorari petition in September 2005. This case amply demonstrates the fallacy of Pfizer's argument, as the very same legal dispute has arisen yet again. Indeed, this exact same legal issue would have reached this Court earlier had Pfizer not manipulated the system to moot Apotex's attempt to challenge

the *Teva* decision last year.[1] And the Generic Pharmaceutical Association highlights the sweeping effect that the *Teva* decision is having on other generic manufacturers also attempting to resolve patent issues such as those presented here. (*See* GPhA Amicus Br. at 18-19). Thus, the *Teva* decision inevitably will continue to directly injure consumers and the public health unless addressed by this Court.

Equally as important, the harm caused by the Federal Circuit's erroneous decision will continue to plague generic drug companies and consumers for years to come. Pfizer claims that enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "Medicare Amendments"), so altered the Hatch-Waxman Act scheme that the questions presented in Apotex's petition will not arise in the future. (*See* Pfizer Opp'n at 10-14). Not so.

First, the changes to which Pfizer refers only apply to drug products for which the first ANDA containing a so-called "Paragraph IV" certification was filed *after* December 8, 2003. Thus, many, many ANDAs continue to be controlled by the statutory scheme at issue in this appeal. The significant legal issues raised herein will, therefore, continue to exist for years.

Second, court decisions continue to play a key role with respect to ANDAs governed by the new Medicare Amendment provisions. Before the Medicare Amendments, a judgment of invalidity, unenforceability, or noninfringement of an Orange Book patent triggered the first

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[1] In 2003, Apotex filed a declaratory judgment action in an effort to obtain patent certainty with respect to its generic equivalent of Pfizer's Accupril®. A district court dismissed the suit, however, for lack of a case or controversy because Pfizer itself refused to file suit. *See TorPharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004). Apotex appealed. Upon learning that the panel in the case included two judges (Mayer and Gajarsa) who had in previous cases expressed the view that a case or controversy exists in these circumstances, Pfizer mooted Apotex's appeal by sending it a covenant not to sue. *See Apotex v. Pfizer*, 125 Fed. Appx. 987 (Fed. Cir. 2005).

ANDA filer's 180-day exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II). As Pfizer points out, those Amendments removed court decisions as something that can trigger generic exclusivity. From this, Pfizer suggests that the Medicare Amendments eliminated the "concern" that led to Apotex's declaratory judgment suit (and similarly to Teva's). (Pfizer Opp'n at 11). This, too, is incorrect.[2]

While the Medicare Amendments removed court decisions as something that could "trigger" the start of the 180-day generic exclusivity period, the Amendments did not eliminate the importance of court decisions. Indeed, Congress elevated such decisions to a position of greater consequence—court decisions now cause an ANDA applicant to *forfeit exclusivity entirely*, and not just start the 180-day clock running. Specifically, under the Medicare Amendments, if the first ANDA filer does not launch its generic product within 75 days of such a judgment, the first filer forfeits its exclusivity altogether. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb), (j)(5)(D)(ii).[3] Thus, the need to ob-

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[2] Pfizer's argument also is nonsensical because it leaves unexplained why Congress would specifically provide for a declaratory judgment remedy for generic companies in the very amendments that, according to Pfizer, eliminated the need for the remedy. Indeed, one searches Pfizer's opposition (and the decision below) in vain for any explanation as to why Congress would go to the trouble of amending the Hatch-Waxman Act specifically to authorize declaratory judgment actions if, as Pfizer contends, Congress simply intended to maintain the legal *status quo*.

[3] In full, the so-called "failure to market" forfeiture provision provides that exclusivity is forfeited if:

> The first applicant fails to market the drug by the later of—
>
> (aa) the earlier of the date that is—
>
> (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
>
> (BB) 30 months after the date of submission of the application of the first applicant; or

tain court decisions using the declaratory judgment provisions that Congress included in the Medicare Amendments remains and, in fact, is more critical now than ever.[4]

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) [of this section] is withdrawn by the holder of the application approved under subsection (b) [of this section].

21 U.S.C. § 355(j)(5)(D)(i)(I).

[4] Pfizer points to an earlier version of the Medicare Amendments that would have deemed an Orange Book patentee's failure to commence an infringement suit to "establish[] an actual controversy . . . sufficient to confer subject matter jurisdiction . . . ." (Pfizer Opp'n at 25 (citation omitted)). But Congress rejected this version, not because it sought to preserve the "reasonable apprehension" test, as Pfizer argues, but rather because the Justice Department advised Congress that the attempt to define an "actual controversy" would usurp the power of the courts to determine the scope of Article III. (*See* Br. of United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer as *Amicus Curiae* in Support of Petition of Teva Pharmaceuticals USA, Inc. for Rehearing or Rehearing *En Banc* at 4-5, No. 04-1186 (Fed. Cir.)). The bill, as enacted, preserved the proper sphere of judicial authority by creating a cause of action, and directing courts to exercise jurisdiction unless it would violate Article III to do so.

Finally, the important legal issues raised by Apotex's petition are not "narrowly fact-intensive" or "unusual" issues unsuited for certiorari review, as Pfizer argues. (*See* Pfizer Opp'n at 12-13). While the application of the Federal Circuit's "reasonable apprehension of imminent litigation" test may at times turn on the particular facts of a case, the question of whether that test is mandated by Article III purely is a legal issue.

For these reasons, Pfizer's arguments against granting certiorari lack merit. The issues raised herein undoubtedly are appropriate for review by this Court. *See* SUP. CT. R. 10.

II. Apotex's Claim For Declaratory Relief Is Ripe.

Pfizer tries to avoid the fact that the decision below represents a split in the circuit and an impermissible departure from this Court's Article III precedent by attempting to re-cast that decision as an application of settled ripeness principles. (Pfizer Opp'n at 14-15). Pfizer's attempt fails. Neither the Federal Circuit nor Pfizer ever characterized the issue here in ripeness terms, or invoked this Court's ripeness cases in support of the denial of subject matter jurisdiction. They failed to do so for good reason. Under this Court's formulation of the test for ripeness—which Pfizer never mentions—Apotex's declaratory judgment action is ripe. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967) (requiring courts "to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration").

Apotex seeks to resolve a patent infringement claim where an act of infringement already has occurred. By statute, Apotex's submission of an ANDA containing a Paragraph IV certification constitutes a statutory act of infringement. 35 U.S.C. § 271(e)(2). As this Court has stated, Congress created this statutory provision for the express purpose of creating an actual controversy sufficient to support judicial resolution of disputes concerning the application of Orange Book patents to proposed generic drugs.

See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).

Pfizer cannot deny that an infringement claim in response to a generic company's submission of an ANDA with a Paragraph IV certification would be ripe. Pfizer has commenced such actions many times, including one against IVAX on the very patent at issue here. Under well-settled law from this Court, if Pfizer could have asserted a ripe claim for patent infringement against Apotex, then Pfizer cannot dispute the ripeness of Apotex's declaratory judgment action to resolve the identical claim: "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the [justiciability] inquiry is the same in either case." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (citation omitted). If Apotex's infringement claim is unripe, then so is the infringement claim authorized by 35 U.S.C. § 271(e)(2), but as this Court previously observed, without suits, the Hatch-Waxman Act scheme simply "will not work." *Eli Lilly*, 496 U.S. at 678.

Moreover, unlike the claims in cases such as *Texas v. United States*, 523 U.S. 296, 300 (1998) (*see* Pfizer Opp'n at 15), Apotex's claim does not "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Apotex's submission of a Paragraph IV ANDA constitutes a statutory act of infringing Pfizer's patent. The patent's validity depends on facts antedating its issuance, and resolution of the infringement claim turns on applying the claims in that patent to a drug product that Apotex already has developed, manufactured, and described in great detail in its ANDA. Given these undisputed facts, there is nothing contingent or hypothetical about the claim that Apotex seeks to resolve and, therefore, this is not a case in which "the courts would benefit from further factual development of the issues presented." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998).

Further, Apotex does not seek to challenge a statute that may never be enforced or whose enforcement is committed to other branches of government. *Cf. Boyle v. Landry*, 401 U.S. 77, 80-81 (1971) (declining to enjoin enforcement of criminal statutes at the behest of individuals who have never even been threatened with prosecution; companion case to *Younger v. Harris*, 401 U.S. 37 (1971)).[5] Congress specifically bestowed sole responsibility on federal courts to hear and decide declaratory judgment actions brought by ANDA applicants under the circumstances presented here.

In sum, the infringement and validity issues raised in Apotex's complaint are fit for judicial resolution. No further factual development is needed to resolve them, and there is no question that Apotex faces hardship if these issues are not resolved. The Federal Circuit so recognized, (*see* Pet. App. at 40a), and Pfizer has not disputed this point (*see* Pfizer Opp'n at 11, 24). Thus, Apotex's claim is ripe for judicial review.

III. The Federal Circuit Ruling Below Conflicts With Prior Decisions Of This Court And Other Circuits.

One of the principal purposes of the Declaratory Judgment Act was to allow competitors to obtain "patent certainty" in the face of what an earlier Federal Circuit decision referred to as a "Damoclean threat with a sheathed sword." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988) (citation omitted). Sixteen years later, the panel majority in *Teva* changed its mind in, ruling that companies like Apotex cannot seek de-

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[5] Pfizer's suggestion that "[t]he Federal Circuit's 'reasonable apprehension' test is a well-established analogue to the imminent threat of prosecution standard," (Pfizer Opp'n at 16), falls far wide of the mark. The federalism concerns that underlie cases such as *Boyle* (*id.* at 15-16) are immaterial here. Nor is there any administrative action with which resolution of Apotex's lawsuit will interfere. On the contrary, under the Hatch-Waxman Act, the timing of FDA action depends on judicial resolution of patent disputes.

claratory relief unless the sword is out of the sheath and, further, that Article III mandates this result. That ruling is, therefore, inconsistent with the Article III jurisprudence of this Court and of other circuit courts. None of Pfizer's arguments to the contrary—which merely mischaracterize the decisions cited in Apotex's Petition—changes this fact. Pfizer necessarily fails to reconcile the Federal Circuit's "reasonable apprehension of imminent litigation" requirement with the Article III decisions of this Court and the decisions from other circuits that have applied this Court's decisions.

Pfizer argues that declaratory judgment claims in *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 237 (1937), were proper in that case because the declaratory judgment defendants had placed Aetna on notice of an adverse legal position by claiming disability benefits in 1930 and 1931. (*See* Pfizer Opp'n at 18). This Court's opinion, however, never suggests that suit by the declaratory judgment defendants was "imminent" based on legal positions staked out several *years* before Aetna brought suit in 1934. This Court found the controversy to be justiciable because the issues were, as they are here, concrete, and a decision on them would conclusively resolve an existing legal dispute.

Pfizer attempts to undermine the significance of this Court's decision in *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), by suggesting that it was a ripeness action and that the decision was consistent with the reasonable apprehension test in requiring the prospect of imminent suit. (Pfizer Opp'n at 17). Again, not so. In that decision, the Court expressly recognized "the sad and saddening scenario that led to enactment of the Declaratory Judgment Act" and that the mere "desire to avoid the threat of a 'scarecrow' patent . . . may therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act." *Cardinal Chem.*, 508 U.S. at 95-96.

These are the very circumstances supporting jurisdiction under the Hatch-Waxman Act in this appeal.

Pfizer attempts to explain away the decisions from other circuits that reject the Federal Circuit's "reasonable apprehension of imminent suit" requirement, but Pfizer's efforts are not persuasive. (*See* Pfizer Opp'n at 18-19). Pfizer, for example, reads *United Christian Scientists* and *Sherwood Medical Industries* as consistent with the Federal Circuit's ruling (Pfizer Opp'n at 18-19), only by ignoring what the District of Columbia and Eighth Circuits, respectively, actually said in each of those cases. The courts in both of those cases recognized, among other things, that the *threat* of an infringement suit, even if implicit, would support a justiciable controversy. *United Christian Scientists v. Christian Sci. Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1158 n.25 (D.C. Cir. 1987); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727-28 (8th Cir. 1975). In addition, those circuits also accorded weight to the fact that the patentee had previously brought infringement actions. *See United Christian Scientists*, 829 F.2d at 1158 n.25; *Sherwood Med.*, 512 F.2d at 728. The circumstances here meet the standards applied by these circuits, particularly in light of Pfizer's representation that the '699 patent could be involved as a basis for infringement and Pfizer's prior suit against IVAX on the same patent at issue here. And, of course, Pfizer does not dispute that the court in *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), did not require the plaintiff to prove that he faced a reasonable apprehension of suit. *Sallen*, 273 F.3d at 25. Indeed, the contours of the dispute between Apotex and Pfizer are no less certain than they were in *Sallen*: the issue is whether Pfizer's patent is valid, and whether Apotex's generic sertraline product infringes.

In the end, Pfizer cannot avoid this Court's decisions defining Article III's "constitutional minimum" in terms of injury in fact attributable to the defendant's conduct that is redressable by the relief requested. Nor can

Pfizer avoid the fact that the Federal Circuit's decision below, which elevates the "reasonable apprehension" test to a Constitutional requirement, plainly is inconsistent with this Court's Article III decisions.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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